UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

COMMONWEALTH OF PENNSYLVANIA and STATE OF NEW JERSEY, Plaintiffs, v. DONALD J. TRUMP, *in his official capacity as President of the United States*; ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; STEVEN T. MNUCHIN, *in his official capacity as Secretary of the Treasury*; UNITED STATES DEPARTMENT OF THE TREASURY; RENE ALEXANDER ACOSTA, *in his official capacity as Secretary of Labor*; UNITED STATES DEPARTMENT OF LABOR; and UNITED STATES OF AMERICA. Defendants.	**No. 2:17-cv-04540-WB**

PLAINTIFFS' STATEMENT OF UNDISPUTED MATERIAL FACTS

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In support of their Motion for Summary Judgment, the Commonwealth of Pennsylvania and the State of New Jersey (the "States") respectfully submit the following Statement of Undisputed Material Facts:

I. The Women's Health Amendment

1. During consideration of the Patient Protection and Affordable Care Act, the Senate passed the "Women's Health Amendment," sponsored by Senator Barbara Mikulski of Maryland. S. Amdt. 2791, 111th Congress (2009–2010).

2. In offering the amendment, Senator Mikulski stated, "Women are often faced with the punitive practices of insurance companies. No. 1 is gender discrimination. Women often pay more and get less. For many insurance companies, simply being a woman is a preexisting condition. Let me repeat that. For many insurance companies, simply being a woman is a preexisting condition." J.A. 2378.

3. Speaking in support of the Women's Health Amendment, Senator Kirstin Gillibrand stated, "In America today, too many women are delaying or skipping preventive care because of the costs of copays and limited access. In fact, more than half of women delay or avoid preventive care because of its cost. This fundamental inequity in the current system is dangerous and discriminatory and we must act." J.A. 2437.

4. During consideration of the Women's Health Amendment, at least six different senators mentioned "family planning" as a service that the amendment would cover or potentially cover. J.A. 2435 (Sen. Boxer); J.A. 2437 (Sen. Gillibrand); J.A. 2438 (Sen. Mikulski); J.A. 2423 (Sen. Cardin); J.A. 2423 (Sen. Feinstein); J.A. 2526 (Sen. Murray).

5. The Women's Health Amendment was included in the final version of the ACA, which became law on March 23, 2010.

II. The Institute of Medicine Report

6. Following passage of the ACA, HRSA commissioned the Institute of Medicine (IOM), to issue recommendations identifying the preventive services for women to be covered by the Women's Health Amendment.

7. The IOM convened a committee of sixteen members, including specialists in disease prevention, women's health issues, adolescent health issues, and evidence-based guidelines, to formulate specific recommendations to develop these recommendations.

8. On July 19, 2011, the IOM Committee issue its report, entitled *Clinical Preventive Services for Women: Closing the Gaps*.

9. The IOM Report recommended that HRSA include "the full range of Food and Drug Administration-approved contraceptive methods, sterilization procedures, and patient education" as a required preventive service for women. J.A. 335.

10. The IOM Report cited evidence that "contraception and contraceptive counseling are effective at reducing unintended pregnancies." J.A. 335.

In recommending the inclusion of contraceptive methods and education in the HRSA Guidelines, the IOM Report made the following assertions:

> 11. "Numerous health care professional associations and other organizations recommend the use of family planning services as part of preventive care for women, including ACOG [American College of Obstetricians and Gynecologists], AAFP [American Academy of Family Physicians], the American Academy of Pediatrics (AAP), the Society of Adolescent Medicine, the AMA [American Medical Association], the American Public Health Association, the Association of Women's Health, Obstetric and Neonatal Nurses, and the

March of Dimes. In addition, the CDC recommends family planning services as part of preventive visits for preconception health (Johnson et al., 2006)." J.A. 429.

12. "Unintended pregnancy is highly prevalent in the United States. In 2001, an estimated 49 percent of all pregnancies in the United States were unintended—defined as unwanted or mistimed at the time of conception—according to the National Survey of Family Growth (Finer and Henshaw, 2006)." J.A. 427.

13. "Although certain subgroups of women are at greater risk for unintended pregnancy than others (e.g., women aged 18 to 24 years, unmarried women, women with low incomes, women who are not high school graduates, and women who are members of a racial or ethnic minority group), all sexually active women with reproductive capacity are at risk for unintended pregnancy." J.A. 428.

14. "[W]omen with unintended pregnancies are more likely than those with intended pregnancies to receive later or no prenatal care, to smoke and consume alcohol during pregnancy, to be depressed during pregnancy, and to experience domestic violence during pregnancy." J.A. 428.

15. Babies born as a result of unintended pregnancies face "significantly increased odds of preterm birth and low birth weight" and are "less likely to be breastfed or are breastfed for a shorter duration." J.A. 428.

16. "Pregnancy spacing is important because of the increased risk of adverse pregnancy outcomes for pregnancies that are too closely spaced (within 18 months of a prior pregnancy). Short interpregnancy intervals in particular have

been associated with low birth weight, prematurity, and small for gestational age births (Conde-Agudelo et al., 2006; Fuentes-Afflick and Hessol, 2000; Zhu, 2005). In addition, women with certain chronic medical conditions (e.g., diabetes and obesity) may need to postpone pregnancy until appropriate weight loss or glycemic control has been achieved (ADA, 2004; Johnson et al., 2006)." J.A. 428.

17. Pregnancy "may be contraindicated for women with serious medical conditions," including pulmonary hypertension, cyanotic heart disease, and Marfan Syndrome." J.A. 428.

18. "[E]vidence exists that "greater use of contraception within the population produces lower unintended pregnancy and abortion rates nationally." J.A. 430.

19. "It is thought that greater use of long-acting, reversible contraceptive methods-including intrauterine devices and contraceptive implants that require less action by the woman and therefore have lower use failure rates-might help further reduce unintended pregnancy rates (Blumenthal et al., 2011)." J.A. 433.

20. "Studies show that as the rate of contraceptive use by unmarried women increased in the United States between 1982 and 2002, rates of unintended pregnancy and abortion for unmarried women also declined (Boonstra et al., 2006)." J.A. 430.

21. "Other studies show that increased rates of contraceptive use by adolescents from the early 1990s to the early 2000s was associated with a decline in teen pregnancies and that periodic increases in the teen pregnancy rate are

associated with lower rates of contraceptive use (Santelli and Melnikas, 2010)." J.A. 430.

22. "For example, the non-contraceptive benefits of hormonal contraception include treatment of menstrual disorders, acne or hirsutism, and pelvic pain. (ACOG, 2010a)." J.A. 432.

23. "Long-term use of oral contraceptives has been shown to reduce a woman's risk of endometrial cancer, as well as protect against pelvic inflammatory disease and some benign breast diseases." J.A. 432.

24. "Despite increases in private health insurance coverage of contraception since the 1990s, many women do not have insurance coverage or are in health plans in which copayments for visits and for prescriptions have increased in recent years." J.A. 434.

25. "In fact, a review of the research on the impact of cost sharing on the use of health cue services found that cost-sharing requirements, such as deductibles and copayments, can pose barriers to care and result in reduced use of preventive and primary care services, particularly for low-income populations." J.A. 434.

26. "Cost barriers to the use of the most effective contraceptive methods are important because long-acting, reversible contraceptive methods [LARCs] and sterilization have high up-front costs (Trussell et al., 2009)." J.A. 433.

27. "A recent study conducted by Kaiser Permanente found that when out-of-pocket costs for contraceptives were eliminated or reduced, women were

more likely to rely on more effective long-acting contraceptive methods (Postlethwaite et al., 2007).” J.A. 434.

28. The IOM Report included statistics on the “Percentage of U.S. Women Experiencing an Unintended Pregnancy During First Year of Typical Use and First Year of Perfect Use, by Contraceptive Method.” It defined “typical use” as use “[a]mong typical couples” and “perfect use” as using a method “both consistently and correctly.” J.A. 431.

29. The Report found that the failure rates for three long-acting, reversible contraceptive methods (Intrauterine Devices ParaGard (copper T) and Mirena (LNG-IUS), and Implanon) were all below one percent. J.A. 431.

30. The Report found that the failure rate for birth control pills (both “[c]ombined pill and progestin-only pill”) was eight percent under “typical use” and 0.3 percent under “perfect use.” J.A. 431.

31. The Report found that the failure rate for male condoms without spermicides was fifteen percent under “typical use” and two percent under “perfect use.” J.A. 431.

III. The Contraceptive Mandate and its Implementing Regulations

32. In July 2010, prior to the issuance of the IOM report, the Departments of Health and Human Services, Labor, and the Treasury issued interim final rules on the Women’s Health Amendment and other provisions of the ACA relating to preventive medicine. These interim rules noted the ACA’s requirement that plans cover preventive services for women pursuant to guidelines issued by HRSA and stated that HHS was “developing these guidelines and expects to issue them no later than August 1, 2011.” J.A. 564.

A. HRSA Guidelines

33. On August 1, 2011, HRSA adopted the recommendations of the report and issued its first "Women's Preventive Services Guidelines," consistent with the Women's Health Amendment. J.A. 310–12.

34. Consistent with the recommendations of the IOM committee, the guidelines required health plans to cover "All Food and Drug Administration approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity." J.A. 311.

35. In 2016, HRSA updated the Guidelines but retained the requirement that plans cover contraception methods and counseling. J.A. 180–82.

36. In 2017, HRSA updated the Guidelines but retained the requirement that plans cover contraception methods and counseling. J.A. 96–97.

B. The Government's Compelling Interest in Enforcing the Contraceptive Mandate

37. Prior to October 2017, Defendants consistently recognized that they had a compelling government interest in enforcing the contraceptive mandate because contraception and contraceptive counseling are safe, effective, and beneficial preventive services for women.

38. The FDA—a component of Defendant HHS—has approved and cleared 18 methods of contraception for women. Ex. 147.

39. The FDA does not approve a method of contraception unless it is proven safe and effective. Ex. 148 ("New drugs and certain biologics must be proven safe and effective to FDA's satisfaction before companies can market them in interstate commerce. . . . If FDA grants an approval, it means the agency has determined that the benefits of the product outweigh the known risks for the intended use.").

40. The Women's Health Amendment reflected Congress's determination "that both existing health coverage and existing preventive services recommendations often did not adequately serve the unique health needs of women." J.A. 301.

41. As a result, costs borne disproportionally by women "imposed financial barriers that prevented women from achieving health outcomes on an equal basis with men." J.A. 256 (citing Ex. 19); *accord* J.A. 300.

42. One of these unique health care needs arises from women's ability to become pregnant. J.A. 241 (citing Exs. 19, 134); J.A. 300 (same).

43. Defendants adopted the IOM Report and other studies demonstrating that unintended pregnancy poses health risks for women and fetuses. *E.g.*, J.A. 300 (citing Ex. 19); J.A. 241 (citing Exs. 19, 128, 129, 130, 136); J.A. 256.

44. Contraceptive coverage, the Departments concluded, prevents these health risks by "reducing the number of unintended and potentially unhealthy pregnancies." J.A. 301.

45. Contraception also "improves the social and economic status of women." J.A. 301 (citing Exs. 127, 131, 132, 135); *accord* J.A. 242 (same).

46. Because "cost sharing can be a significant barrier to access to contraception," "eliminating cost sharing is particularly critical to addressing the gender disparity" that motivated Congress to pass the Women's Health Amendment in the first place. J.A. 242 (citing Exs. 19, 133); *accord* J.A. 301 (same).

47. As recently as January 2017, Defendants asserting "the government's compelling interest in ensuring that women receive full and equal health coverage, including contraceptive coverage." J.A. 173.

IV. Comments on the Interim Final Rules

48. In the Final Rules, Defendants stated that they received approximately 110,000 comments posted to Regulations.gov. J.A. 5, 60.

49. The Administrative Record, as produced, contained many duplicate or near-duplicate comments from the same individual or organization. It appears that many identical or similar comments were submitted by the same individual or organization to both the docket for the Religious Exemption IFR and the Moral Exemption IFR. Defendants did not distinguish between the two dockets in the Administrative Record.

50. The actual number of comments was significantly greater due to thousands of form comments, all of which opposed the Rules. For example, one PDF in the Administrative Record contains 29,139 pages, each page with approximately a dozen form comments opposing the Rules. CD 12, Bates 715547.

51. Almost all of the comments opposed the Rules.[1]

52. Only 27 comments (representing 17 unique individuals or organizations) supported the Rules. Exs. 106–120.[2]

53. Thirteen comments (representing nine unique individuals or organizations) did not clearly take a position for or against the Rules. Exs. 121–126.[3]

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[1] The Joint Appendix contains selected comments opposing the Rules. Most organizations filed similar or identical comments to both dockets. Generally, the Joint Appendix contains the comment filed to the docket for the Religious Exemption IFR.

[2] Where an identical comment supporting the Rules was produced multiple times in the Administrative Record, the Joint Appendix contains only one copy of that comment. The number 27 refers to the number of total comments, including duplicates, located in the Administrative Record.

[3] Where the same comment neither supporting nor opposing the Rules was produced multiple times in the Administrative Record, the Joint Appendix contains only one copy of that

54. Of the 110,000 comments counted by Defendants, 0.025% supported the Rules and 99.96% opposed the Rules.

55. Many commenters stated that contraception is a vital preventive service for women:[4]

a. "Contraceptive efficacy at preventing unintended pregnancy is supported by decades of rigorous evidence and by the government itself.[5] . . . In truth, contraception enables women, including teens, to prevent

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comment. The number 13 refers to the number of total comments, including duplicates, located in the Administrative Record.

[4] Excerpted quotes are not intended to be comprehensive of all commenters. Footnotes included within quotes are lifted directly from the comment.

[5] *See, e.g.*, Institute of Medicine, (2011), Clinical Preventive Services for Women: Closing the Gaps, Washington, DC: The National Academies Press; American College of Obstetricians and Gynecologists. (2016, December), Women's Preventive Services Initiative: Recommendations for Preventive Services for Women Final Report to the U.S. Department of Health and Human Services, Health Resources & Services Administration (p. 82-91), Retrieved 27 November 2017, from https://www.womenspreventivehealth.org/final-report/; Trussell, J. (2011, May), Contraceptive failure in the United States, Contraception, 83(5), 397-404; Hatcher, R.A., Trussell, J., Nelson, AL., Cates, W., Kowal, D., & Policar, M.S. (Eds.). (2011). Contraceptive Technology (20th ed.), Atlanta, GA: Bridging the Gap Communications; Declaration of Dr. Lawrence Finer in Support of Plaintiffs' Motion for Preliminary injunction at 4-5, California v. Wright, No. 4:17-cv-05783-HSG (Nov. 9, 2017) ("Sexually active couples using no method of contraception have a roughly 85% chance of experiencing a pregnancy in a one-year period, while the risk for those using a contraceptive method ranges from 0.05% to 28%.") (citing Sundaram, A., Vaughan, B., Bankole, A., Finer, L., Singh, S., & Trussell, J. (2017, March), Contraceptive failure in the United States: Estimates from the 2006-2010 National Survey of Family Growth, Perspectives on Sexual and Reproductive Health, 49(1), 7-16); Peipert, J.F., Madden, T., Allsworth, J.E., & Secura, G.M. (2012, December), Preventing unintended pregnancies by providing no-cost contraception, Obstetrics & Gynecology, 120(6), 1291-1297; Finer, L.B., & Zolna, M.R. (2016, March), Declines in unintended pregnancy in the United States, 2008-2011, New England Journal of Medicine, 374(9), 843-852; Harper, C.C., Rocca, C.H., Thompson, K.M., Morfesis, J., Goodman, S., Darney, P.B., . . . Speidel, J.J. (2015, June), Reductions in pregnancy rates in the USA with long-acting reversible contraception: A cluster randomized trial, The Lancet, 386(9993), 562-568; Speidel, JJ., Harper, C.C., & Shields, W.C. (2008, September), The potential of long-acting reversible contraception to decrease unintended pregnancy, Contraception, 78(3), 197-200.

unintended pregnancy and control the timing of a desired pregnancy.[6] The Centers for Disease Control and Prevention named family planning one of the ten great public health achievements of the past century,[7] and family planning is widely credited for contributing to women's societal, educational, and economic gains.[8]" *E.g.*, J.A. 632 (American Academy of Nursing Comments).

56. Many commenters stated that contraception does not pose serious health risks:

a. "As with any medication, certain types of contraception may be contraindicated for patients with certain medical conditions, including high blood pressure, lupus, or a history of breast cancer.[9,10] Specifically, the IFR suggests an increased risk of venous thromboembolism (VTE). In fact, VTE among oral contraceptive users is very low and much lower than the risk of VTE during pregnancy or in the immediate postpartum

[6] *See, e.g.*, Boonstra, H.D. (2014, September 3). What is behind the declines in teen pregnancy rates? *Guttmacher Policy Review*, 17(3), 15-21; Lindberg, L., Santelli, J., & Desai, S. (2016, November), Understanding the decline in adolescent fertility in the United States, 2007-2012, *Journal of Adolescent Health*, 59(5), 577-583.

[7] Centers for Disease Control and Prevention. (2013, April 26). *Ten Great Public Health Achievements in the 20th Century*, Retrieved 27 November 2017, from https://www.cdc.gov/about/history/tengpha.htm.

[8] *See, e.g.*, Sonfield, A., Hasstedt, K., Kavanaugh, M.L., & Anderson, R. (2013, March). *The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children*, Retrieved 30 November 2017, from the Guttmacher Institute website: https://www.guttmacher.org/sites/default/files/report_pdf/social-economic-benefits.pdf.

[9] Progestin-only hormonal birth control: pill and injection. FAQ No. 86. American College of Obstetricians and Gynecologists. July 2014.

[10] Combined hormonal birth control: pill, patch, and ring. FAQ No. 185. American College of Obstetricians and Gynecologists. July 2014.

period.[11] The IFR also suggests contraception increases the risk of breast cancer, but there is no proven increased risk of breast cancer among contraceptive users, particularly those under 40.[12]" J.A. 1064 (NARAL ProChoice America Comments); *see also* J.A. 605 (AccessNow Comments), J.A. 622 (ACLU Comments); J.A. 651 (American Congress of Obstetricians and Gynecologists, American Academy of Pediatrics, & Society for Adolescent Health and Medicine Comments); J.A. 659 (American Public Health Association Comments); J.A. 665 (American Society for Emergency Contraception Comments); J.A. 684 (Asian & Pacific Islander American Health Forum Comments); J.A. 789 (Center for Inquiry & Secular Coalition for America Comments); J.A. 803 (Colorado Consumer Health Initiative Comments); J.A. 878 (Family Planning Councils of America Comments); J.A. 946 (Ibis Reproductive Health Comments); J.A. 1025 (Lift Louisiana Comments); J.A. 1088 (National Asian Pacific American Women's Forum); J.A. 1138 (National Family Planning & Reproductive Health Association Comments); J.A. 1173 (National Institute for Reproductive Health Comments); J.A. 1193 (National Latina Institute of Reproductive Health Comments); J.A. 1295–95 (Physicians for Reproductive Health Comments); J.A. 1306 (Power to

[11] Risk of venous thromboembolism among users of drospirenone-containing oral contraceptive pills. Committee Opinion No. 540. American College of Obstetricians and Gynecologists. Obstet Gynecol 2012;120:1239-42.

[12] Curtis KM, Jatlauoui TC, Tepper NK, et al. US Selected Practice Recommendations for Contraceptive Use, 2016. MMWR Recomm Rep 2016;65(No. RR-4):1-66. DOI: http://dx.doi.org/10.15585/mmwr.rr6504a1.

Decide Comments); J.A. 1341 (Public Health Solutions Comments); J.A. 1354 (Raising Women's Voices for the Health Care We Need Comments); J.A. 1371 (Reproductive Rights and Justice Practicum at Yale Law School Comments); J.A. 1454 (Wisconsin Alliance for Women's Health Comments); J.A. 1468 (Women's Health and Family Planning Alliance of Texas Comments); J.A. 1481 (Women's Law Project Comments t); J.A. 1496 (Yale Students for Reproductive Justice Comments).

b. "The Departments go further, selectively interpreting data in order to overstate 'negative health effects' associated with contraceptives. This includes misleading assertions of an association between contraceptive use, breast cancer, and cervical cancer, as well as vascular events and 'risky sexual behavior.' The Departments ignore substantial evidence to the contrary, and ignore the balance of significant non-contraceptive health benefits associated with contraceptive use." J.A. 1072 (NARAL Pro-Choice Maryland Comments); *see also* J.A. 1215 (National Partnership for Women & Families, Jacobs Institute of Women's Health, Union of Concerned Scientists Comments); J.A. 1323 (Professor James Trussell, Princeton University Comments).

c. "It is especially irresponsible to misrepresent the risks of breast and cervical cancer without accurately reporting the substantial evidence of contraceptives' association with cancer prevention, since any evaluation of preventative health care should fully weigh the risks and benefits.

Contraceptives are associated with a reduced risk of colorectal cancer;[13] endometrial cancer is 50 percent less likely among women who use oral hormonal contraceptives for at least one year compared to women who have never used oral hormonal contraceptives;[14] oral hormonal contraceptives can reduce the risk of ovarian cancer by 27 percent, and 20 percent for every five years of additional use;[15] oral hormonal contraceptives can lower the risk of hereditary ovarian cancer in women with BRCA1 or BRCA2 gene mutations;[16] and oral hormonal contraceptive use for more than 10 years can lower the risk of ovarian cancer among women with endometriosis, who are typically at higher risk of developing ovarian cancer.[17]" J.A. 1027 (NARAL Pro-Choice Maryland Comments); *see also* J.A. 665 (American Society for Emergency Contraception Comments); J.A. 1194–95 (National Latina Institute of Reproductive Health Comments; J.A. 1314 (Planned Parenthood Federation of American & Planned Parenthood Action Fund Comments); J.A. 1323 (Professor James Trussell, Princeton University Comments).

[13] Schindler, A.E. (2013). Non-contraceptive benefits of oral hormonal contraceptives. *International Journal of Endocrinology and Metabolism, 11*(1), 41-47.

[14] *Id.*

[15] *Id.*

[16] *Id.*

[17] *Id.*

57. Many commenters stated that contraception does not terminate pregnancy and therefore is not an abortifacient:

a. "FDA-approved contraceptive methods are not abortifacients. Every FDA-approved contraceptive acts before implantation, does not interfere with a pregnancy, and is not effective after a fertilized egg has implanted successfully in the uterus, which is when pregnancy begins.[18]" J.A. 1063 (NARAL Pro-Choice America); *see also* J.A. 605 (AccessMatter Comments); J.A. 647 (American Congress of Obstetricians and Gynecologists, American Academy of Pediatrics, & Society for Adolescent Health and Medicine Comments); J.A. 684 (Asian & Pacific Islander American Health Forum Comments); J.A. 803 (Colorado Consumer Health Initiative Comments); J.A. 947 (Ibis Reproductive Health Comments); J.A. 1073–74 (NARAL ProChoice Maryland Comments); J.A. 1087 (National Asian Pacific American Women's Forum Comments); J.A. 1193 (National Latina Institute of Reproductive Health Comments); J.A. 1230 (National Partnership for Women and Families Comments);J.A. 1276 (National Women's Law Center Comments); J.A. 1295 (Physicians for Reproductive Health Comments); J.A. 1306 (Power to Decide); J.A. 1341 (Public Health Solutions Comments); J.A. 1353–54 (Raising Women's Voices for the Health Care We Need Comments); J.A.

[18] Brief for Physicians for Reproductive Health, American College of Obstetricians and Gynecologists et al. as Amici Curiae Supporting Respondents, Sebelius v. Hobby Lobby, 573 U.S. XXX (2014) (No. 13-354). Available at acog.org/~/media/Departments/Government%20Relations%20and%29Outreach/20131021AmicusHobby.pdf?.

1370–71 (Reproductive Rights and Justice Practicum at Yale Law School Comments); J.A. 1454 (Wisconsin Alliance for Women's Health Comments), J.A. 1468 (Women's Health and Family Planning Alliance of Texas Comments); J.A. 1481 (Women's Law Project Comments); J.A. 1495–96 (Yale Students for Reproductive Justice Comments).

58. Many commenters stated that increased access to contraception is not associated with increased sexual activity. To the contrary, increased access to contraception is associated with lower teen pregnancy rates:

a. "Increased access to contraception is not associated with increased unsafe sexual behavior or increased sexual activity.[19,20] In fact, research has shown school-based health centers that provide access to contraceptives are proven to increase use of contraceptives by already sexually active students, not to increase onset of sexual activity.[21,22] On the other hand, young females who did not use birth control at first sexual intercourse were twice as likely to become pregnant.[23] Overall, increased access to

[19] Kirby D. Emerging answers 2007: Research findings on programs to reduce teen pregnancy and sexually transmitted diseases. Washington, DC: The National Campaign to Prevent Teen and Unplanned Pregancy. 2009.

[20] Meyer JL, Gold MA, Haggerty CL. Advance provision of emergency contraception among adolescent and young adult women: a systematic review of literature. J Pediatr Adolesc Gynecol. 2011;24(1);2-9).

[21] Minguez M, Santelli JS, Gibson E, Orr M, & Samant, S. Reproductive health impact of a school health center. Journal of Adolescent health, 2015;56(3), 338-344.

[22] Knopf JA, Finnie RKC, Peng Y, et al. Community Preventative Services Task Force. School-based health centers to advance health equity: a Community Guide systematic review. American Journal of Preventative Medicine 2016;51(1):114-26.

[23] *Id.*

and use of contraception has contributed to a dramatic decline in rates of adolescent pregnancy.[24] More females are using contraception the first time they have sex.[25]" J.A. 1064 (NARAL Pro-Choice America Comments).

b. "Unintended pregnancies account for nearly half of the 6.1 million pregnancies annually in the U.S. and 75% of teenage pregnancies. All taxpayers carry the burden of these costs as two-thirds (68%) of the 1.5 million unplanned births that occurred in 2010 were paid for by public insurance programs, primarily Medicaid." J.A. 1033 (Commonwealth of Massachusetts Executive Office of Health and Human Services Comments)

c. "Teen pregnancy is also at the lowest point in at least 80 years.[26]" J.A. 1072 (NARAL Pro-Choice Maryland).

d. "The supplemental information also fails to consider important research on the impact of positive outcomes associated with reducing barriers to

[24] Lindberg L, Santelli J, Desai S. Understanding the Decline in Adolescent Fertility in the United States, 2007-2012. J Adolesc health. 2016;59(5):577-583. DOI: 10.1016/j.jadohealth.2016.06.024.

[25] *Id.*

[26] Declaration of Dr. Lawrence Finer in Support of Plaintiffs' Motion for Preliminary Injunction at 8, California v. Wright, No. 4:17-cv-05783-HAS (Nov. 9, 2017) ("In 2013, the U.S. pregnancy rate among 15-19 year olds was at its lowest point in at least 80 years and had dropped to about one-third of a recent peak in 1990.") (citing Kost, K, Maddow-Zimet, I., & Arpaia, A. (2017, August). *Pregnancies, Births and Abortions Among Adolescents and Young Women in the United States, 2013: National and State Trends by Age, Race and Ethnicity*. Retrieved 27 November 2017, from the Guttmacher Institute website: https://www.guttmacher.org/sites/default/files/report_pdf/us-adolescent-pregnancy-trends-2013.pdf).

contraceptive access. One study not cited in the register, where over 9,000 women were provided the contraceptive method of their choice at no cost, found that eliminating barriers to contraception can significantly decrease the rates of teen birth, abortion rates, and repeat abortions, and may also reduce the rate of unintended pregnancies.[27] At the same time, the Centers for Disease Control and Prevention's High School Youth Risk Behavior Survey Data shows declines in teens who have ever had sex, are currently sexually active, or have had sex with four or more partners between 2011 and 2015.[28] These findings weaken the Administration's claim that expanded access to contraception will lead to more risk-taking among women." J.A. 1283 (New York City Comments).

e. "Contraception for all girls and women should be voluntary and free. Research shows that making it so leads to dramatic declines in the teen pregnancy rate. Take the state of Colorado. Between 2009 and 2013, when the state provided free long acting reversible contraception, the teen birth rate, abortion rate, and pregnancy rate among unmarried women under 25 who do not have a high school degree fell by 40 plus percent. . . . Access to birth control has particularly important consequences for educational attainment because of the timing of high school and college degrees. The bottom line is access to free contraception can mean the difference

[27] Peipert, J., Madden T., Allsworth, J., & Secura G. (2012). Preventing Unintended Pregnancies by Providing No-Cost Contraception. *Obstetrics & Gynecology*, 120(6), 1291-1297.

[28] Centers for Disease Control and Prevention (CDC), *1991-2015 High School Youth Risk Behavior Survey Data*.

between completing high school and college and not." J.A. 1360 (Representatives of Education and Youth Development Communities Comments).

59. Many commenters stated that contraception is important to women's health and equality:

a. "Women face a unique set of health care challenges because they access more health services than men, yet earn less on average than men.[29]" J.A. 598 (AccessMatters Comments).

b. "Unintended pregnancies have higher rates of long-term health complications for women and their infants. Women with unintended pregnancies are more likely to delay prenatal care, leaving their health complications unaddressed and increasing risk of infant mortality, birth defects, low birth weight, and preterm birth. Women with unintended pregnancies are also at higher risk for maternal morbidity and mortality, maternal depression, and experiencing physical violence during pregnancy.[30]" J.A. 599 (AccessMatters Comments).

c. "Birth control is also vital in furthering equal opportunity for women, enabling women to be equal participants in the social, political, and economic life of the nation. By enabling women to decide if and when to

[29] U.S. Census Bureau. Income, Poverty, and Health Insurance Coverage in the United States: 2008, Table A-2. 2009

[30] Conde-Agudelo A, Rosas-Bermudez A, Kafury-Goeta AC. Birth spacing and risk of adverse perinatal outcomes: a meta-analysis. JAMA 2006;295:1809-23; 19 Tsui AO, McDonald-Mosley R, Burke AE. Family Planning and the Burden of Unintended Pregnancies. Epidemiologic Reviews. 2010;32(1):152-174. doh 1 0.1093 /epirev/mxg012

become parents, birth control allows women to access more professional and educational opportunities. . . . Studies show that access to contraception has increased women's wages and lifetime earnings.[31] In fact, the availability of the oral contraceptive pill alone is associated with roughly one-third of the total wage gains for women born from the mid-1940s to early 1950s.[32] Access to oral contraceptives may also account for up to one-third of the increase in college enrollment by women in the 1970s,[33] which was followed by large increases in women's presence in law, medicine, and other professions.[34]" J.A. 1057 (NARAL Pro-Choice America Comments).

d. "The Department of Health and Human Services has previously acknowledged that the contraceptive coverage benefit enables "women to achieve equal status as health and productive members of the job force." (77 Fed. Reg. 8725, 8728). Lower education, career level, and earnings are

[31] See, Jennifer J. Frost & Laura Duberstein Lindberg, Reasons for Using Contraception: Perspectives of US Women Seeking Care at Specialized Family Planning Clinics, 87 CONTRACEPTION 465, 467 (2013); Adam Sonfield, et al., Guttmacher Ist., The Social and Economic Benefits of Women's Ability to Determine Whether and When to Have Children (2013), available at http://

[32] See Martha J. Bailey et al., The Opt-in Revolution? Contraception and the Gender Gap in Wages, 19, 26 (Nat'l Bureau of Econ. Research Working Paper o. 17922, 2012), http://www.nber.org/papers/wl 7922 (last visited Feb. 9, 2016); Claudia Goldin & Lawrence F. Katz, The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions, 110 J. Pol. Econ. 730, 749 (2002).

[33] Heinrich H. Hock, The Pill and the College Attainment of American Women and Men 19 (Fla. State Univ., Working Paper 2007).

[34] Claudia Goldin & Lawrence F. Katz, The Power of the Pill: Oral Contraceptives and Women's Career and Marriage Decisions, 110 J. Pol. Econ. 730, 749 (2002), https://dash.harvard.edu/handle/1/2624453.

important social determinants of health, and can be considered social risk factors for poor health outcomes. Access to birth control enables women to be more financially secure, which mitigate [sic] social risk and improve health." J.A. 1095 (National Center for Health Research).

e. "By improving women's social and economic status, access to contraception promotes equal opportunities far beyond the health care realm. Contraception allows women to decide if and when to become parents, creating more professional and educational opportunities. Indeed, the U.S. Supreme Court found that "[t]he ability of women to participate equally in the economic and social life of the Nation has been facilitated by their ability to control their reproductive lives."[35] Increased control over reproductive decisions in turn, provides women with educational and professional opportunities that have increased gender equality over the decades since birth control was introduced." J.A. 1147 (National Health Law Program Comments).

f. "[R]esearch links women's access to contraception with increases in the pursuit of professional degrees and career paths with higher pay and prestige, which leads to women's increased earning power and the narrowing of the gender pay gap. Expanding opportunities for employers to deny providing contraceptive coverage will reverse the positive trends

[35] *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 856 (1992); *see also Erickson v. Bartell Drug Co.*, 141 F. Supp. Ed 1266, 1273 (W.D. Wash. 2001) ("[T]he adverse economic and social consequences of unintended pregnancies fall most harshly on women and interfere with their choice to participate fully and equally in the marketplace.") (internal quotations omitted).

toward achieving gender parity, and have a tremendous adverse effect on women's health and well-being." J.A. 1249 (New York State Department of Financial Services Comments).

g. "Significantly, access to contraceptive coverage has given women the option to delay childbearing and pursue additional education, spend additional time in their careers, and increase earning power over the long-term. One-third of the wage gains women have made since the 1960s have been attributed to access to oral contraceptives.[36] Access to birth control has helped narrow the wage gap between women and men. The decrease in the wage gap among 25 to 49-year-olds between men's and women's annual incomes would have been 10 percent smaller in the 1980s and 30 percent smaller in the 1990s in the absence of widespread legal birth control access for women.[37]" J.A. 1386 (State Attorneys General Comments).

V. The Final Religious and Moral Exemption Rules

60. On November 7, 2018, the Agencies issued two new rules that "finalize" the IFRs "with changes based on public comments." J.A. 1–55 (Final Religious Exemption Rule); J.A. 56–95 (Final Moral Exemption Rule).

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[36] *Birth Control Has Expanded Opportunity for Women – in Economic Advancement, Educational Attainment, and Health Outcomes*, Planned Parenthood 1,1 (June 2015, http://www.plannedparenthood.org/files/1614/3275/8659/BC_factsheet_may2015_updated_1.pdf.

[37] *See* Martha J. Bailey et al., *The Opt-In Revolution? Contraception and the Gender Gap in Wages* 27 (Nat'l Bureau of Econ. Research, Working Paper No. 17322, 2012), http://www-personal.umich.edu/~baileymj/Opt_In_Revolution.pdf.

61. Defendants estimated that at least 70,515 and at most 126,400 women will lose contraceptive coverage when their employers claim exemptions under the Rules. J.A. 40–47; 89–92.

62. The first number, 70,515, represented the Defendants' estimate based on the number of employers that have litigated against the contraceptive mandate or who took advantage of the accommodation.

63. Defendants estimated the number of women affected by currently litigating employers who will use the new religious exemption as follows:

64. Defendants began with an estimate that the employers still litigating over the mandate employ 49,000 persons. J.A. 40–41; *see* Ex. 140.

65. Because 60% of employees, on average, are covered by their employer's health benefits, Defendants estimated that the litigating employers employ 29,000 persons. J.A. 41. Sixty percent of 49,000 is actually 29,400.

66. Defendants estimated that each employer policyholder has one dependent, resulting in 58,000 covered persons. J.A. 41. (Should be 58,800.)

67. Because women of childbearing age (15-44) constitute 20.2% of the U.S. population, and because 43.6% of women use contraception covered by the Guidelines, Defendants estimated that 5,200 women would be affected by the loss of contraceptive coverage. J.A. 41.

68. Defendants also estimated that educational institutions litigating over the mandate provide student plans that cover 2,600 students. J.A. 41. Assuming that half of those students are women and that each has a dependent of

childbearing age, Defendants estimated that 1,150 female students would be affected by the loss of contraceptive coverage. J.A. 41.

69. This results in a total of 6,400 women who work for a litigating employer or study at a litigating school and who would lose contraceptive coverage. J.A. 41.

70. Defendants estimated the number of women affected by currently accommodated employers who will use the new religious exemption as follows:

71. Defendants began by noting that in 2017, there were 1,823,000 employees and beneficiaries covered by plans offered by self-insured employers who took advantage of the accommodation and whose Third Party Administrators (TPAs) sought reimbursement under the fee adjustment provision, 45 C.F.R. § 156.50(d)(3)(iii). J.A. 41.

72. Defendants assumed that all TPAs for self-insured plans using the accommodation sought user fee adjustments in 2017. J.A. 42.

73. The Department of Labor estimates that, among persons covered by employer-sponsored insurance in the private sector, 37.3 percent were covered by fully insured plans. J.A. 42. Extrapolating from the number of persons covered by plans offered by self-insured employers using the accommodation, Defendants estimated that 1,084,000 000 employees and beneficiaries were covered by fully-insured plans using the accommodation. J.A. 42.

74. This resulted in a total of 2,907,000 employees and beneficiaries covered by plans taking advantage of the accommodation. J.A. 42.

75. Defendants then assumed that these 2,907,000 employees and beneficiaries are associated with only 209 entities are using the accommodation. J.A. 41.

76. Defendants assumed that 100 entities would continue to use the accommodation. J.A. 42.

77. Defendants then assumed that these 100 entities would account for 75% of all persons covered by accommodated plans. J.A. 42.

78. Correspondingly, the 109 entities that will use the new exemptions represent only 25% of all persons currently covered by accommodated plans. J.A. 42. Defendants calculated this figure to be 797,000 persons. J.A. 43.

79. Applying the percentage of women of childbearing age (20.2%) and percentage of women who use contraception covered by the Guidelines (43.6%), Defendants calculated that 64,000 woman who are covered by currently accommodated entities would lose coverage. J.A. 43.

80. Combining the number of women affected by litigating entities claiming the new religious exemption with the number of women affected by accommodated entities claiming the new religious exemption, Defendants estimated that 70,500 women would lose contraceptive coverage due to the Final Religious Exemption Rule. J.A. 43.

81. Defendants estimated that 15 women would lose contraceptive coverage due to the Final Moral Exemption Rule, as follows:

82. In the absence of any data, Defendants estimated that nine nonprofit entities will use the moral exemption. J.A. 89–90. Defendants then

assumed that these entities would only hire persons who share their moral convictions, just as churches generally only hire persons who share their religious convictions. J.A. 90. Therefore, they estimated that no woman working for a nonprofit that uses the moral exemption would be affected. J.A. 90.

83. Defendants also assumed that no institute of higher education would use the moral exemption. J.A. 90

84. In the absence of any data, Defendants estimated that nine for-profit entities would use the moral exemption. J.A. 91.

85. Defendants then assumed that these nine entities would employ fewer than 100 employees and an average of 9 policyholders. J.A. 91.

86. Assuming that each policyholder has one dependent, Defendants calculated that 162 covered persons could work for for-profit employers using the moral exemption. J.A. 91.

87. Applying the same percentage of women of childbearing age (20.2%), but a different percentage of women who use contraception covered by the Guidelines (44.3%), Defendants calculated that 15 woman would lose coverage due to the Final Moral Exemption Rule. J.A. 91.

88. The second number, 126,400, estimates the number of women currently working for employers who did not provide contraceptive coverage prior to the ACA:

89. Defendants began by calculating that 64.2 million women under age 65 were covered by private sector employer-sponsored insurance in 2017. J.A. 43–44. Defendants then eliminated the 5% of women who are covered by employer-sponsored plans but do not use their employer-sponsored plan as their

primary source of health insurance. J.A. 44. This resulted in 61 million women. J.A. 44. Defendants further eliminated the 3.8% of women who are self-employed, resulting in 58.7 million women. J.A. 44.

90. Using data about grandfathered plans, Defendants then estimated that 49 million women under 65 years of age received primary health insurance coverage from private sector, third party employment-based non-grandfathered plans. J.A. 44.

91. Because 46.7% of women under age 65 are of childbearing age, Defendants calculated that 22.9 million of childbearing age received primary health insurance coverage from private sector, third party employment-based non-grandfathered plans. J.A. 44.

92. Data shows that prior to the ACA, 6% of employers did not offer contraception and 31% did not know whether they offered contraceptive coverage. J.A. Using the 6% figure only, as well as percentage of women who use contraception covered by the Guidelines (43.6%), Defendants estimated that 599,000 women of childbearing age who use contraception were covered by plans that omitted contraceptive coverage prior to the ACA. J.A. 44.

93. Defendants then assumed that no publicly traded company would use the new religious exemption. This eliminated the 31.3% of employees in the private sector who work for publicly traded companies, leaving 411,000 women. J.A. 44.

94. Next, Defendants attempted to calculate how many women work for employers already exempt under the Church Exemption. Defendants estimated

that there are approximately 24,200 Catholic churches and integrated auxiliaries in the United States. J.A. 45. They noted that Guidestone, a self-insured church plan organized by the Southern Baptist Convention, covers 38,000 employers. J.A. 45. They also noted that Christian Brothers, a self-insured church plan covering Catholic organizations, covers the 24,000 Catholic churches and auxiliaries listed above as well as 500 additional entities not exempt as churches. J.A. 45. In total, Defendants estimated 62,000 church and church plan employers. J.A. 45. Using the number of persons covered by Guidestone (220,000) as transferable ratio, Defendants calculated that 32,100 women of childbearing age who use contraceptive work for already-exempted employers. J.A. 45.

95. In sum, Defendants estimated that 379,000 women of childbearing age who use contraception work for private, non-publicly traded employers that did not cover contraception pre-ACA and are not exempt under the Church Exemption. J.A. 45.

96. Defendants then assumed that only one third of these employers would be able to claim the new religious exemption. J.A. 45. Therefore, only 126,400 women would be impacted. J.A. 45.

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